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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,899	01/09/2002	Nicholas L. Abbott	061818-5002-US04	3817
43850 7590 07/10/2008 MORGAN, LEWIS & BOCKIUS LLP (SF) One Market, Spear Street Tower, Suite 2800 San Francisco, CA 94105				
EXAMINER LUNDGREN, JEFFREY S				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/044,899

Applicant(s)

ABBOTT ET AL.

Examiner

JEFFREY S. LUNDGREN

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 129-202 is/are pending in the application.
- 4a) Of the above claim(s) 129-143, 146, 147 and 155-202 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 144, 145 and 148-154 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

Claims 129-202 are pending in the instant application; claims 129-143, 146, 147 and 155-202 are withdrawn; claims 144, 145 and 148-154 are the subject of the Office Action below.

Election of the Invention

Applicants assert that their original election was made with traverse and request reconsideration.

Applicants original traversal made in the paper filed on August 8, 2006, is on the grounds that each of the claims "emerges as a common idea or concept."

However, the standard for a proper restriction requirement is whether the inventions are patently distinct and a burdensome search would be presented to the Office by searching multiple inventions. Since Applicants did not point out the alleged error in the restriction requirement, and did not convey how "common ideas or concepts" relate to the aforementioned criteria, such arguments are unpersuasive.

The requirement is still deemed proper and is therefore made FINAL.

Substitute Declaration - Defective

The substitute declaration is defective because certain inventors have not signed (*i.e.*, Dubrovsky and Skaife). See 37 CFR § 1.52.

Objection to the Abstract Under 37 C.F.R. § 1.72

The objection to the Abstract is withdrawn in view of Applicants' amendment.

Claim Rejections - 35 USC § 112 - Withdrawn

The previous grounds of rejection are withdrawn in view of Applicants' amendments to the claims.

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Claim Rejections - 35 USC § 102 - Withdrawn

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 144, 145 and 148-154, are rejected under 35 U.S.C. § 102(e) as being anticipated by Abbott *et al.*, U.S. Patent No. 6,284,197 B1, issued on September 4, 2001, is withdrawn for the reasons presented by Applicants.

The rejection of claims 144, 145, and 148-154, under 35 U.S.C. § 102(b) as being anticipated by Gupta *et al.*, *Science* 279:2077-2080 (1998), is withdrawn for the reasons presented by Applicants.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 144, 145, and 148-154, under 35 U.S.C. § 102(a) as being anticipated by Gupta *et al.*, *Science* 279:2077-2080 (1998), is maintained.

Applicants allege that the rejection should be withdrawn because the invention described in Gupta is not by another, but that of the named inventorship. Applicants indicate that a copy of the "Katz" declaration provided in a related application is provided as Appendix A.

However, the declaration that Applicants reference has not been provided to the Office; accordingly the rejection is maintained.

Claim 144 is directed to a method for detecting an analyte, comprising contacting with said analyte a recognition moiety for said analyte, wherein said contacting causes at least a portion of a plurality of mesogens proximate to said recognition moiety to detectably switch from a first orientation to a second orientation upon contacting said analyte with said recognition moiety; and detecting said second orientation of said at least a portion of said plurality of mesogens, whereby said analyte is detected.

Abbott discloses a device and methods for detecting analytes (see e.g. Abstract; col. 1, lines 22-27; col. 5, lines 13-59; col. 6, lines 54-65; col. 13, lines 4-31; col. 14, lines 6-32).

"It has now been discovered that liquid crystals can be used to amplify, and transduce into an optical signal, the interaction of a wide array of molecules with various surfaces. The interaction of the molecule with the surface can be converted into an easily detected optical output.

A variety of surfaces, including spontaneously organized surfaces, can be designed so that molecules, on interacting with these surfaces, trigger changes in the orientations of films of mesogenic compounds. ***When the molecule interacting with the surface has a size on the order of a protein, the interaction can result in the reorientation of approximately 10⁵-10⁶ mesogens per molecule.*** Interaction-induced changes in the intensity of light transmitted through the mesogenic layer can be easily seen with the naked eye."

Abbott, col. 5, lines 13-26 (emphasis added); and:

"In a third aspect, the present invention provides a device for detecting an interaction between an analyte and a recognition moiety, said device comprising: a first substrate having a surface; a second substrate having a surface, said first substrate and said second substrate being aligned such that said surface of said first substrate opposes said surface of said second substrate; a first organic layer attached to said surface of said first

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substrate, wherein said organic layer comprises a first recognition moiety which interacts with said analyte; and a mesogenic layer between said first substrate and said second substrate, *said mesogenic layer comprising a plurality of mesogens, wherein at least a portion of said plurality of mesogens undergo a detectable switch in orientation upon interaction between said first recognition moiety and said analyte, whereby said interaction between said analyte and said first recognition moiety is detected.*"

Abbott, col. 14, lines 15-32 (emphasis added). Accordingly, claim 144 is anticipated.

Claims 150 and 151 are anticipated by Abbott's teaching of "the interaction can result in the reorientation of approximately 105-106 mesogens per molecule" in the captioned paragraphs above.

Claim 152 is anticipated by Abbott's teaching in Fig. 2 (see configurations of mesogenic compounds before and after analyte detection), and description thereof.

Claim 153 and 154 are anticipated by Abbott's teaching of visual observation and/or microscopy (see Figs. 1C, and 3A-3I; and description thereof).

Further, the device is multilayered and comprises one or more substrates, an organic layer, a recognition moiety, and a mesogenic layer (see col. 5, lines 13-59; col. 13, lines 4-31; col. 14, lines 6-32). The substrate includes materials such as glass or organic polymers (see col. 6, lines 54-65; col. 14, line 45 thru col. 15, line 10; col. 15, line 59 thru col. 16, line 14; and Fig. 2).

The surface of the substrate disclosed by Abbott is patterned with features such as grooves and ridges with emphasis on the texture:

"The nature of the surface of the substrate has a profound effect on the anchoring of the mesogenic layer which is associated with the surface. The surface can be engineered by the use of mechanical and/or chemical techniques. The surface of each of the above enumerated substrates can be substantially smooth. Alternatively, the surface can be roughened or patterned by rubbing, etching, *grooving*, stretching, oblique deposition *or other similar techniques known to those of skill in the art. Of particular relevance is the texture of the surface which is in contact with the mesogenic compounds.*"

Abbott, col. 16, lines 47-57 (emphasis added).

With regard to the size of the aforementioned, Abbott generally identifies certain techniques for creating these features and their scale:

“The *size and complexity of the pattern on the substrate is limited only* by the resolution of the technique utilized and *the purpose for which the pattern is intended*. For example, using microcontact printing, features as small as 200 nm have been layered onto a substrate. See, Xia, Y.; Whitesides, G., *J. Am. Chem. Soc.* 117:3274-75 (1995). Similarly, using photolithography, patterns with features as small as 1 μm have been produced. See, Hickman et al., *J. Vac. Sci. Technol.* 12:607-16(1994). Patterns which are useful in the present invention include those which comprise features such as wells, enclosures, partitions, recesses, inlets, outlets, *channels, troughs, diffraction gratings and the like*.”

Abbott, col. 17, lines 7-18 (emphasis added).

As in claim 149, Abbott teaches the following regarding recognition moieties and the analytes that bind to the recognition moieties:

“In another preferred embodiment, the recognition moiety is a biomolecule. In still further preferred embodiments, *the biomolecule is a protein, antibody, peptide, nucleic acid (e.g., single nucleotides or nucleosides, oligo nucleotides, polynucleotides and single- and higher-stranded nucleic acids) or a combination thereof*. In a presently preferred embodiment, the recognition moiety is biotin.”

Abbott, col. 26, lines 30-36 (emphasis added); and:

“Recognition moieties which are antibodies can be used to recognize analytes which are *proteins, peptides, nucleic acids, saccharides or small molecules* such as drugs, herbicides, pesticides, industrial chemicals and agents of war.”

Abbott, col. 29, lines 10-22 (emphasis added). These samples meet the limitations of claims 145 and 148.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 144, 145, and 148-154, on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 6,284,197, either on its own, or in view of Gupta *et al.*, *Science* 279:2077-2080 (1998), is maintained.

Applicants have not provided a terminal disclaimer, nor provided arguments traversing the rejection. Accordingly, the rejection is maintained.

The express limitations of claims 144, 145, and 148-154 of the instant application, and certain teachings of Gupta have been detailed above, and are herein incorporated by reference.

Specifically, claim 1 of the '197 patent is directed to a method of visually detecting an analyte-recognition moiety complex formed by an interaction between an analyte and a recognition moiety for said analyte by transducing said interaction to an organic mesogenic layer, said method comprising:

- (a) interacting said analyte with a surface comprising said recognition moiety, thereby forming an analyte-recognition moiety complex, said surface

comprising: (i) a substrate; (ii) a self-assembled organosulfur or organosilane monolayer bound to substrate; and (iii) said recognition moiety bound to said self-assembled monolayer;

(b) contacting said analyte-recognition moiety complex with said organic mesogenic layer, thereby anchoring said organic mesogenic layer onto said self-assembled monolayer and causing at least a portion of a plurality of mesogens proximate to said recognition moiety to detectably switch from a first orientation to a second orientation, thereby transducing said interaction to said mesogenic layer, said transducing causing said mesogenic layer to register a visually detectable feature; and

(c) visually detecting said feature.

The rejection of claims 144, 145, and 148-154, on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 6,852,285, is withdrawn in view of the terminal disclaimer.

Conclusions

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsius verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James (Doug) Schultz, can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JSL/

/JD Schultz, PhD/

Supervisory Patent Examiner, Art Unit 1635